

**510(k) Summary Of Safety and Effectiveness**

FEB - 4 2009

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SDMA of 1990 and 21 § 807.92

**Establishment:**

**Address:** PreAnalytiX GMBH  
Feldbachstrasse,  
Hombrechtikon Switzerland CH-8634

**Registration Number:** 3005202328

**Contact Person:** M. Wendy Ballesteros  
Regulatory Affairs Manager  
Telephone no.: 201-847-6280  
Fax No. 201-847-4858

**Date of Summary:** August 1, 2008

**Device:**

**Trade Name:** PAXgene™ Blood RNA System  
**Classification Name:** RNA Preamplification Systems  
**Classification:** Class II  
**Regulation:** 21 CFR 866.4070  
**Product Code:** NTW  
**Panel** Immunology  
**Performance Standards:** None Established under 514 of the Food, Drug and Cosmetic Act

**Intended Use**

The PAXgene™ Blood RNA System consists of a blood collection tube (PAXgene™ Blood RNA Tube) and nucleic acid purification kit (PAXgene™ Blood RNA Kit). It is intended for the collection, storage, and transport of blood and stabilization of intracellular RNA in a closed tube and subsequent isolation and purification of host RNA from whole blood for RT-PCR used in molecular diagnostic testing.

Performance characteristics for the PAXgene™ Blood RNA System have only been established with "cfos and IL1B." The user is responsible for establishing appropriate PAXgene™ Blood RNA System performance characteristics for other target transcripts.

**Device Description:**

The PAXgene™ Blood RNA System consists of:

- PAXgene™ Blood RNA tubes
- PAXgene™ Blood RNA kit.

The PAXgene™ Blood RNA tube is of a sterile, plastic, evacuated blood collection tube containing stabilization solution (tetradecyl trimethyl-ammonium oxalate and tartaric acid. These components serve to lyse cells, protect RNA molecules from degradation by ribonucleases (RNases) and prevent induction of gene expression. The kit consists of 5 aqueous buffer solutions for resuspending, binding, washing, and eluting RNA, RNase-free water, proteinase K, an RNase-Free DNase set, spin columns, microcentrifuge tubes, processing tubes, and secondary blood collection tube closures.

**Substantial Equivalence:**

Based on comparison of the device features, materials, intended use and performance, the PAXgene™ Blood RNA System is shown to be substantially equivalent to the commercially available PAXgene™ Blood RNA System as described in K042613, cleared on April 14, 2005.

The PAXgene™ Blood RNA System described in this submission differs from the predicate device as described in K042613 as follows:

1. Change in operating principal to allow automation of the PAXgene™ Blood RNA System sample purification process on QIAGEN's QIAcube instrument.

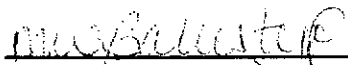
Operating Principal of Principal Device	Operating Principal of Predicate Device
The PAXgene™ Blood RNA System that enables the collection, stabilization, storage, and transportation of whole blood specimens, together with <b>rapid and efficient manual and automated protocols</b> for purification of intracellular RNA. The system requires the use of PAXgene Blood RNA Tubes for blood collection and RNA stabilization, followed by RNA purification using the PAXgene Blood RNA Kit.	The PAXgene™ Blood RNA System that enables the collection, stabilization, storage, and transportation of whole blood specimens, together with a rapid and efficient protocol for purification of intracellular RNA. The system requires the use of PAXgene Blood RNA Tubes for blood collection and RNA stabilization, followed by RNA purification using the PAXgene Blood RNA Kit.

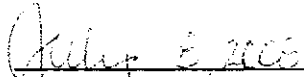
2. Change in Buffer BR5 (Elution Buffer) volume from 5 mL to 6 mL.

Principal Device			Predicate Device		
Buffer BR5 (Elution Buffer)	6 ml	Ammonium sulfate	Buffer BR5 (Elution Buffer)	5 ml	Ammonium sulfate

**Summary of Design Control Activities:**

The Design Control activities performed demonstrated the RNA obtained from the QIAcube is compatible with molecular diagnostic applications such as mRNA transcript level determination by RT-PCR. Therefore the processing of RNA by the automated protocol on QIAGEN's QIAcube is equivalent to the manual process as described in K042613.

  
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M. Wendy Ballesteros  
Regulatory Affairs Manager  
BD Diagnostics - Preanalytical Systems  
Becton Dickinson and Company

  
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Date



**FEB -4 2009**

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

PreAnalytiX GmbH  
c/o Becton Dickinson and Co.  
Ms. Wendy Ballesteros  
Regulatory Affairs Manager  
1 Becton Drive, MC 312  
Franklin Lakes, NJ 07417

Re: k082150

Trade/Device Name: PAXgene™ Blood RNA System  
Regulation Number: 21 CFR 866.4070  
Regulation Name: RNA Preanalytical Systems  
Regulatory Class: Class II  
Product Code: NTW  
Dated: December 05, 2008  
Received: January 15, 2009

Dear Ms. Ballesteros:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

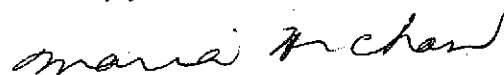
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding

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of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Maria M. Chan", is written over a horizontal line.

Maria M. Chan, Ph.D.  
Acting Division Director  
Division of Immunology and Hematology Devices  
Office of In Vitro Diagnostic Device Evaluation  
and Safety  
Center for Devices and Radiological Health

Enclosure

### Indication for Use

510(k) Number (if known):

Device Name: PAXgene™ Blood RNA System

Indication For Use:

PAXgene Blood RNA Kit is for the purification of intracellular RNA from whole blood collected in the PAXgene Blood RNA Tube. When the kit is used in conjunction with the PAXgene Blood RNA Tube, the system provides purified intracellular RNA from whole blood for RT-PCR used in molecular diagnostic testing.

Performance characteristics for the PAXgene Blood RNA System have only been established with FOS and IL1B gene transcripts. The user is responsible for establishing appropriate PAXgene Blood RNA System performance characteristics for other target transcripts.

Prescription Use  X   
(21 CFR Part 801 Subpart D)

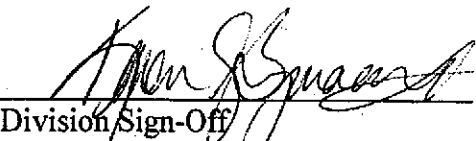
And/Or

Over the Counter Use    
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)  K082150